IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and TAKEDA PHARMACEUTICALS AMERICA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

H. Lundbeck A/S ("Lundbeck"), Takeda Pharmaceutical Company Ltd. ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda USA"), Takeda Pharmaceuticals International AG ("Takeda International"), and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively, "Lundbeck and Takeda" or "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin" or "Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Defendants' recent submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 211105 (hereinafter, "Defendants' ANDA"). Through Defendants' ANDA, Defendants seek approval to market generic versions of Plaintiffs' pharmaceutical product

TRINTELLIX®, prior to the expiration of United States Patent No. 9,861,630 ("the '630 Patent").

THE PARTIES

2. Plaintiff H. Lundbeck A/S ("Lundbeck") is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Lundbeck is the assignee and owner of the '630 Patent.

3. Plaintiff Takeda Pharmaceutical Company Ltd. is a corporation organized and existing under the laws of Japan, with a place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan. Lundbeck has granted Takeda Japan an exclusive license to the '630 Patent in connection with the use, importation, distribution, marketing, promotion, and sale of TRINTELLIX® in the United States.

4. Plaintiff Takeda Pharmaceuticals International AG is a corporation organized and existing under the laws of Switzerland, with a place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland. Takeda International is an indirect wholly owned subsidiary of Takeda Japan. Takeda International has an exclusive sublicense to the '630 Patent from Takeda Japan in connection with the commercialization of TRINTELLIX® in the United States.

5. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda International and Takeda Japan own Takeda USA. Takeda USA holds the New Drug Application ("NDA") No. 204447 for TRINTELLIX® and has an exclusive sublicense to the '630 Patent from Takeda International, which grants it the right to import, distribute, and sell TRINTELLIX® in the United States on behalf of Takeda.

6. Plaintiff Takeda Pharmaceuticals America, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda America is a wholly owned subsidiary of Takeda USA. Takeda America distributes and markets TRINTELLIX® in the United States on behalf of Takeda USA.

7. Lundbeck and Takeda are engaged in the business of creating, researching, developing, and bringing to market revolutionary pharmaceutical products to help treat serious diseases, including major depressive disorder.

8. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

9. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202.

10. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Limited.

11. On information and belief, Lupin Pharmaceuticals, Inc. acts at the direction, and for the benefit, of Lupin Limited, and is controlled and/or dominated by Lupin Limited.

12. On further information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents

of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

13. On information and belief, Lupin Pharmaceuticals, Inc. maintains a website, http://www.lupinpharmaceuticals.com, which states that "Lupin Pharmaceuticals, Inc. is the U.S. wholly owned subsidiary of Lupin Limited," and that Lupin Pharmaceuticals, Inc. is "building on [its] parent company's strengths of vertical integration in discovery research, process chemistry, active pharmaceutical ingredient production, formulation development and regulatory filings." Lupin Pharmaceuticals, Inc.'s website also reports that "Vinita Gupta, CEO of Lupin Pharmaceuticals, Inc. says 'founded on the strengths of our parent company Lupin Limited, Lupin Pharmaceuticals, Inc. intends to bring a portfolio of generics as well as branded products to the US market.'"

14. On information and belief, Lupin Pharmaceuticals, Inc. acts as the U.S. agent for Lupin Limited for purposes of regulatory submissions to the U.S. Food and Drug Administration ("FDA") in seeking approval for generic drugs.

15. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. acted collaboratively in the preparation and submission of ANDA No. 211105.

16. On information and belief, Defendants caused ANDA No. 211105 to be submitted to FDA and seek FDA approval of ANDA No. 211105.

17. On information and belief, Defendants intend to commercially manufacture, market, offer for sale, and sell the vortioxetine hydrobromide tablets described in Defendants' ANDA ("the ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves Defendants' ANDA.

18. On information and belief, Defendants intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the ANDA Products, in the event FDA approved Defendants' ANDA.

JURISDICTION AND VENUE

19. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '630 Patent.

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

21. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, *inter alia*, have continuous and systematic contacts with the State of Delaware, regularly conduct business in the State of Delaware, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, have purposefully availed themselves of the privilege of doing business in the State of Delaware, and intend to sell the ANDA Products in the State of Delaware upon approval of ANDA No. 211105.

22. In a related matter involving Defendants' ANDA and patents related to the '630 Patent, Defendants stated that "Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only." *H. Lundbeck A/S et al v. Lupin Limited et al*, 18-cv-00090-LPS, D.I. 11 (D. Del. March 22, 2018).

23. Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware.

24. On information and belief, Defendants are in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter-egos, which

Defendants manufacture, distribute, market, and/or sell throughout the United States and in this judicial district.

25. On information and belief, Defendants are licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos. On information and belief, Lupin Pharmaceuticals, Inc. holds a current and valid "Pharmacy-Wholesale" License in Delaware.

26. On information and belief, Defendants and/or their subsidiaries actively seek employment of sales representatives to serve customers in the State of Delaware, continuously employ sales representatives in the State of Delaware, and regularly market their products in the State of Delaware.

27. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture TRINTELLIX® for sale and use throughout the United States, including this judicial district. On information and belief and as indicated by a letter dated November 30, 2017 sent by Lupin Limited to H. Lundbeck and Takeda USA pursuant to 21 U.S.C. § 355(j)(2)(B) ("Notice Letter" or "First Notice Letter") and by a letter dated April 6, 2018 sent by Lupin Limited to Lundbeck and Takeda pursuant to 21 U.S.C. § 355(j)(2)(B) ("Second Notice Letter") (collectively, the "Notice Letters"), ANDA No. 211105 was prepared and filed with the intention of seeking to market the ANDA Products nationwide, including within this judicial district.

28. On information and belief, Defendants plan to sell the ANDA Products in the State of Delaware, list the ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Products in the State of

Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

29. On information and belief, Defendants know and intend that their proposed ANDA Products will be distributed and sold in Delaware and will thereby displace sales of TRINTELLIX®, causing injury to Lundbeck and Takeda. Defendants intend to take advantage of their established channels of distribution in Delaware for the sale of their proposed ANDA Products.

30. Lupin Limited has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in a related matter involving Defendants' ANDA and patents related to the '630 Patent. *H. Lundbeck A/S et al v. Lupin Limited et al*, 18-cv-00090-LPS, D.I. 11 (D. Del. March 22, 2018).

31. Lupin Limited and Lupin Pharmaceuticals, Inc. regularly engage in patent litigation concerning FDA-approved drug products in this judicial district, have not contested personal jurisdiction in such litigation, in this judicial district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Omeros Corp. v. Lupin Ltd. et al*, 17-cv-00803, D.I. 9 (D. Del. Aug. 23, 2017); *Bayer Intellectual Prop. GmbH et al v. Lupin Ltd. et al*, 17-cv-01047, D.I. 9 (D. Del. Aug. 22, 2017); *Bristol-Myers Squibb Co. et al v. Lupin Ltd.*, 17-cv-00378, D.I. 8 (D. Del. May 4, 2017); *ViiV Healthcare Co. et al v. Lupin Ltd. et al*, 17-cv-00315, D.I. 8 (D. Del. Apr. 17, 2017); *Astellas Pharma Inc. et al v. Lupin Ltd. et al*, 16-cv-00908, D.I. 20 (D. Del. Jan. 17, 2017); *Arena Pharm., Inc. et al v. Lupin Ltd. et al*, 16-cv-00887, D.I. 12 (Jan. 11, 2017).

32. Venue is proper in this district for Lupin Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Lupin Limited is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

33. In a related matter involving Defendants' ANDA and patents related to the '630 Patent, Defendants stated that "Defendants do not contest venue over Lupin Ltd. in this Court for purposes of this action only." *H. Lundbeck A/S et al v. Lupin Limited et al*, 18-cv-00090-LPS, D.I. 11 (D. Del. March 22, 2018).

34. Venue is proper in this district for Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENT

35. Takeda USA is the holder of New Drug Application ("NDA") No. 204447 for TRINTELLIX® tablets (5 mg, 10 mg, 15 mg, and 20 mg dosage strengths).[1] The active ingredient in TRINTELLIX® is vortioxetine hydrobromide. FDA approved NDA No. 204447 on September 30, 2013.

36. TRINTELLIX® is an oral antidepressant indicated for the treatment of Major Depressive Disorder (MDD). It is an inhibitor of serotonin (5-HT) reuptake, an agonist at 5-HT1A receptors, a partial agonist at 5-HT1B receptors, and an antagonist at 5-HT3, 5-HT1D and 5-HT7 receptors. It is considered to be the first and only drug with this combination of pharmacodynamic activity. It represents a major advancement in the treatment of depression.

[1] Plaintiffs do not sell 15 mg TRINTELLIX ® tablets in the United States.

37. The ’630 Patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “Orange Book”) for TRINTELLIX®.

38. The ’630 Patent, entitled “1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment,” was duly and lawfully issued by the USPTO on January 9, 2018. A true and correct copy of the ’630 Patent is attached hereto as Exhibit A.

DEFENDANTS’ ANDA NO. 211105

39. On information and belief, Defendants have submitted ANDA No. 211105 to FDA, or caused ANDA No. 211105 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of vortioxetine hydrobromide tablets as purported generic versions of TRINTELLIX® tablets prior to the expiration of the ’630 Patent.

40. On information and belief, FDA has not approved Defendants’ ANDA.

41. On information and belief, Lupin Limited sent Lundbeck and Takeda the Second Notice Letter dated April 6, 2018. The Second Notice Letter represented that Lupin Limited had submitted a purported Paragraph IV certification for the ’630 Patent to FDA in connection with ANDA No. 211105. Plaintiffs reserve all rights to challenge the sufficiency of Defendants’ ANDA and Second Notice Letter.

42. On information and belief, the purpose of an ANDA and Paragraph IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products before expiration of the ’630 Patent. Hence, Defendants’ purpose in submitting ANDA No. 211105 is to market the products described therein before the expiration of the ’630 Patent.

43. On information and belief, if approved, the ANDA Products will have the same indication as TRINTELLIX®. On further information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 211105 for the ANDA Products is the treatment of major depressive disorder (MDD).

44. On information and belief, if FDA approves Defendants' ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Products, within the United States, including within the State of Delaware, or will import the ANDA Products into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of the ANDA Products will directly infringe the '630 Patent.

45. On information and belief, if FDA approves Defendants' ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products in a manner that infringes the '630 Patent.

46. This action is being brought within forty-five days of Plaintiffs' receipt of the Second Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C).

CLAIM FOR RELIEF

47. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–46 as if fully set forth herein.

48. On information and belief, Defendants submitted or caused the submission of ANDA No. 211105 to FDA, and thereby seek FDA approval of Defendants' ANDA.

49. On information and belief, Defendants submitted or caused the submission of a Paragraph IV certification for the '630 Patent in ANDA No. 211105.

50. Plaintiffs own all rights, title, and interest in and to the '630 Patent.

51. The ANDA Products fall within one or more claims of the '630 patent.

52. Defendants have infringed at least one claim of the '630 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting a Paragraph IV certification for the '630 Patent in connection with ANDA No. 211105 and thereby seek FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '630 Patent.

53. If approved, the importation, manufacture, sale, offer for sale, or use of the ANDA Products will infringe one or more claims of the '630 Patent under 35 U.S.C. § 271(a).

54. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '630 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce infringement of one or more claims of the '630 Patent. On information and belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the '630 Patent and knowledge that their acts are encouraging infringement.

55. Unless enjoined by this Court, upon FDA approval, Defendants will contributorily infringe the '630 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendants' ANDA, Defendants will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the '630 Patent. On information and belief, Defendants have had and continue to have knowledge of the '630 Patent and knowledge that their acts will lead to infringement of the patent. On information and belief, Defendants have had and continue to have knowledge that the ANDA Products are especially made or especially

adapted for a use that infringes the ’630 Patent and that there are no substantial non-infringing uses for the ANDA Products.

56. Defendants had actual and constructive notice of the ’630 Patent prior to submitting a Paragraph IV certification for the ’630 Patent in connection with ANDA No. 211105, and were aware that submitting a Paragraph IV certification requesting FDA approval for Defendants’ ANDA prior to the expiration of the ’630 Patent would constitute an act of infringement of the ’630 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the ’630 Patent.

57. Defendants submitted a Paragraph IV certification for the ’630 Patent in connection with ANDA No. 211105 without adequate justification for asserting the ’630 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’630 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

58. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’630 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that Defendants have infringed the '630 Patent under 35 U.S.C. § 271(e)(2)(A);

(B) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendants' ANDA shall be no earlier than the expiration date of the '630 Patent, or any later expiration of exclusivity for the '630 Patent, including any extensions or regulatory exclusivities;

(C) Entry of a permanent injunction enjoining Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendants or on their behalf from commercially manufacturing, using, offering for sale, or selling the ANDA Products within the United States, or importing the ANDA Products into the United States, until the expiration of the '630 Patent;

(D) A judgment declaring that making, using, selling, offering to sell, or importing the ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the '630 Patent pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(E) A declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendants or on their behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the ANDA Products, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(F) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

the ANDA Products, or any product that infringes the '630 Patent, or induce or contribute to such conduct, prior to the expiration of the patents;

(G) A finding that this is an exceptional case, and an award of attorneys' fees to Plaintiffs in this action pursuant to 35 U.S.C. § 285;

(H) Costs and expenses in this action; and

(I) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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